

**REMARKS**

Claims 94-101, 110-122 and 132-134 are pending in the subject application. Claims 9-11, 17-19, 33-35, 41, 42, 47, 48, 67, 68, 74-76, 88, 102-109, 123-131 and 135 have been withdrawn. Applicants have hereinabove cancelled claims 9-11, 17-19, 33-35, 41, 42, 47, 48, 67, 68, 74-76, 88 and 94-135 and added new claims 136-155. Accordingly, upon entry of this Amendment, claims 136-155 will be pending and under examination.

In making these amendments, applicants neither concede the correctness of the Examiner's rejections in the February 9, 2004 Final Office Action, nor abandon the right to pursue in a continuing application embodiments of the instant invention no longer claimed in this application.

New claim 136 corresponds to cancelled claims 94, 100 and 101; new claims 137-141 correspond to cancelled claims 95-99, respectively; new claim 142 corresponds to cancelled claims 110, 121 and 122; new claims 143-147 correspond to cancelled claims 111-115, respectively; new claims 148-152 correspond to cancelled claims 116-120, respectively; and new claims 153-155 correspond to cancelled claims 132-134, respectively. Furthermore, support for the term "about" recited in new claims 132 and 136 may be found, *inter alia*, in the specification as follows: page 51, lines 9-28; page 52, line 27 to page 53, line 4; and Figures 1 and 3. Applicants maintain that these amendments to the claims do not raise any issue of new matter, and that these claims are fully supported by

the specification as originally filed. Accordingly, applicants respectfully request that this Amendment be entered.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the February 9, 2004 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

#### **The Claimed Invention**

This invention provides methods of diagnosing a thyroid condition in a subject. One method comprises obtaining a suitable urine sample from the subject, and determining a concentration of thyroid stimulating hormone (TSH) in the sample by a method which is not a radioimmunoassay, wherein (i) a concentration of TSH greater than about 0.35  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, diagnoses hypothyroidism in the subject, and (ii) a concentration of TSH less than about 0.04  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, diagnoses hyperthyroidism in the subject.

Another method comprises obtaining a suitable urine sample from the subject, and determining a concentration of TSH and a concentration of thyroxine in the sample by a method which is not a radioimmunoassay, wherein (i) a concentration of TSH greater than about 0.35  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, and a concentration of thyroxine greater than about 1.5 ng/ml in the subject's

urine diagnoses hypothyroidism in the subject, and (ii) a concentration of TSH less than about 0.04  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, and a concentration of thyroxine less than about 0.3 ng/ml in the subject's urine diagnoses hyperthyroidism in the subject.

This invention is based on applicants' surprising discovery that measuring either (1) urinary TSH or (2) urinary TSH and urinary thyroxine can reliably detect hypothyroidism and hyperthyroidism.

**Rejection Under 35 U.S.C. §103(a) - Obviousness**

The Examiner rejected claims 94-101, 132 and 133 under 35 U.S.C. §103(a) as allegedly unpatentable over Kuku, et al. (Journal of Endocrinology, 1974, Vol. 62, pages 645-655), in view of Schuurs, et al. (U.S. Patent No. 4,016,043).

In response to the Examiner's rejection, but without conceding the correctness thereof, applicants note that these claims have been cancelled. Applicants understand this rejection to instead apply to new claims 136-155, which correspond to the cancelled claims in the manner discussed above. Applicants respectfully point out that new independent claims 136 and 142 recite the specific concentrations of TSH and thyroxine recited in cancelled claims 100, 101, 121 and 122, as applicable.

On page 7, ¶8 of the February 9, 2004 Final Office Action, the Examiner indicated that claims 100, 101 and 121 (and, applicants trust, claim 122) would be allowable if drafted in independent form to incorporate the

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limitations of their respective independent claims, as the specific TSH and thyroxine concentrations recited in these claims do not exist in the combination of references cited by the Examiner. Applicants note that the claims have been so drafted and, thus, the Examiner's rejection is obviated.

The Examiner also rejected claims 110-122 and 134 under 35 U.S.C. §103(a) as allegedly unpatentable over Kuku et al., in view of Schuurs, et al. and Philo, et al. (U.S. Patent No. 5,108,896).

In response, but without conceding the correctness thereof, applicants again note that these claims have been cancelled, and that new claims 136-155 have been added. Applicants maintain that the subject matter of new claims 136-155 is non-obvious over the cited references for the reasons set forth above.

#### Summary


Applicants maintain that new claims 136-155 are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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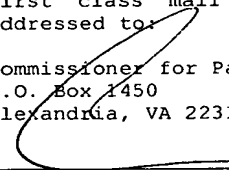
No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

  
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